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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,915	11/02/2001	Anthony J. Mauro	460.2115USU	7768

7590

03/16/2005

Charles N.J. Ruggiero, Esq.
Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
10th Floor
One Landmark Square
Stamford, CT 06901-2682

EXAMINER

ANDERSON, CATHARINE L

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/003,915	Applicant(s) MAURO ET AL.	
	Examiner C. Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005 and 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 11, 13-16, 19-23, 25-27, 29-34 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 11, 13-16, 19-23, 25-27, 29-34 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 January 2005 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-11, 13-14, 19-23, 25-27, 29-32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189).

Baker discloses a tampon, as described in column 13, lines 53-54, comprising a composition disposed in the tampon, as described in column 7, lines 50-52 and 54-55. The composition comprises an anti-bacterial agent and a finishing agent. The anti-bacterial agent is a quaternary ammonium compound, as described in column 5, line 64, to column 7, lines 12, specifically alkyl dimethyl benzyl ammonium chloride and alkyl dimethyl ethylbenzyl ammonium chloride. The finishing agent is a nonionic surfactant, polyethylene glycol, as described in column 5, lines 54-56 and 62. The composition

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further comprises a preservative, as described in column 5, lines 22-27. Baker discloses the composition of the claimed invention, and the antibacterial properties are inherent in the chemicals comprising the composition. Baker therefore inherently discloses a composition effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, and fulfills all limitations of the claims.

Baker discloses the amount of anti-bacterial agent as based on the total weight of the composition, as described in column 30, lines 38-41, invention but remains silent as to the amount of anti-bacterial agent as based on the total weight of the tampon. It would have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising 0.01% to 5% by weight of the anti-bacterial agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Baker discloses the amount of finishing agent as based on the total weight of the composition, as described in column 30, lines 33-33, invention but remains silent as to the amount of finishing agent as based on the total weight of the tampon. It would have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising 0.01% to 10% by weight of the finishing agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

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Claims 15-16 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189) as applied to claims 14 and 32 above, and further in view of Fischetti et al. (6,335,012).

Baker discloses all aspects of the claimed invention with the exception of the surfactant being a polyoxyethylene fatty acid ester. Baker discloses the surfactant may be a polyoxyethylene sorbital ester, as disclosed in column 5, lines 36-38.

Fischetti discloses polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester as being art-recognized equivalent surfactants, as described in column 11, lines 14-16, which are suitable for use in tampons, as described in column 12, lines 20-21 and 26.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to have the surfactant of Baker comprise a polyoxyethylene fatty acid ester, as taught by Fischetti, since the examiner takes official notice of the equivalence of polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester for their use as surfactants in tampons, and the selection of any of these equivalents would be within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 10 January 2005 have been fully considered but they are not persuasive.

In response to the applicant's argument that Baker discloses a tampon in a laundry list of possible devices, it is noted that patents are relevant as prior art for all they contain (see MPEP 2123). The fact that Baker discloses other embodiments aside

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from a tampon is irrelevant. Baker teaches a tampon with a composition deposited therein, and therefore fulfills the claimed limitations.

In response to the applicant's argument that the invention of Baker fails to fulfill the requirements of inherency, it is noted that in the cited case of Rijckaet, the issue was whether or not a diaper having two fasteners would inherently anticipate a diaper having three fasteners. This is not analogous to the instant case, where Baker clearly discloses all the structural limitations of the claimed invention (i.e. a tampon, an antibacterial, a finishing agent). The inherency lies in the ability of the antibacterial to react with bacteria. Since the antibacterial composition disclosed by Baker is of the identical chemical structure as the claimed invention, the composition will exhibit the same physical properties, including reactivity with bacteria (see MPEP 2112.01).

In response to the applicant's argument that Baker fails to disclose the synergistic effect observed in the instant invention, it is noted that Baker merely remains silent as to the synergistic effect, and the lack of disclosure does not prove that the invention of Baker does not exhibit the same effect. As described in the paragraph above, the identical structure will react in the same way.

It is further noted that the instant specification shows, in the table bridging pages 12 and 13, a synergistic effect for 2.5% Tween 20 and 1.0% BTC. The samples having only 0.25% Tween 20 do not perform significantly better than the control. Therefore, the synergistic effect is not observed in the entire range claimed, or with any of the antibacterials listed in the instant specification other than Tween 20. Due to the broadness of the instant claim, the applicant is seeking to claim embodiments for which

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they do not show a synergistic effect. The argument that Baker fails to disclose a synergistic effect is therefore not persuasive.

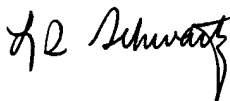
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CNA
cla
March 11, 2005


Larry I. Schwartz
Supervisory Patent Examiner
Group 3700